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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,359	07/23/2003	Daniel M. Deaton	900001-2115	8226
59945 7590 09/10/2007 KOS PHARMACEUTICALS, INC. 1 CEDAR BROOK DRIVE CRANBURY, NJ 08512-3618			EXAMINER LEWIS, KIANDRA CHARLE	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/625,359

Applicant(s)

DEATON ET AL.

Examiner

Kiandra C. Lewis

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3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-15, 45-48, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-15, 45-48, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/2007 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6, 10-15, 45-48, 55 and 56 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-6,10-15,45-48, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor US 6,029,659 in view of Rand US 6,431,168.

As to claims 1, 55 and 56, O'Connor discloses an apparatus for dispensing medication comprising at least one canister 11 containing the medication to be dispensed, the canister 11 being movable in a first and a second direction. O'Connor continues to disclose a mouthpiece 12 providing a point of dispensation for the medication from the canister 11 to a user when the canister is moved in a first direction. In addition, O'Connor discloses a switch means 50 for completing an electrical circuit when the canister 11 moves in a first direction and opening the electrical circuit when the canister 11 moves in a second direction, wherein the switch means 50 is oriented to enable operational connectivity with the canister or canister discharge (see Figure 7). O'Connor includes a counter module 40 for performing a count upon the closure of the electrical circuit and displaying a dispensation history (41) of the medication in the canister 11. O'Connor discloses a seal 718 isolating the counter module 40 from the mouthpiece and the canister to prevent contamination as shown in Figure 7.

O'Connor does not expressly state that there is a ramp contacted by a ferrule portion of the canister in a direction substantially non-axial to the first direction and which acts upon the switch means when the canister is moved in the first direction. Rand however teaches a ramp (16) that comes in contact with a ferrule portion of the canister and acts upon a switch means (18). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have a ramp means as disclosed by Rand in the device of O'Connor for the purpose of supporting the switch.

As to claims 2-4 and 6, O'Connor as modified by Rand teaches the dispensation history that includes the number of doses of medication remaining in the canister.

(column 3, lines 58-61 – O'Connor). In addition, O'Connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

As to claim 5, it would have been obvious to a person having ordinary skill in the art at the time of the invention to allow this device to be capable of varying the period of time for a dosage in order for the device to be reused with different medicines of varying dosage requirements.

As to claim 10, Rand et al. teach the apparatus dispensing medication that includes a switch means 44 with an electrically conductive contact 46/47 imbedded in the seal 40. Therefore, it would have been obvious to a person ordinary skill in the art at the time of the invention to modify the device of O'Connor to replace this switch means with the switch means taught by Rand et al. in order to increase the reaction speed of the switch from movement of the canister as well as improve the accuracy of having a switch react via conductive contact versus force of contact.

As to claims 11 and 12, the above combination teach a portion of the counter module 40 disposed external to the mouthpiece 12 as shown in Figure 5. It is considered a mechanical equivalent to place a portion of the counter module within the mouthpiece. Additionally, it teaches the counter module as being partially disposed within the mouthpiece especially if the mouthpiece includes portion 3 until 20.

Accordingly, the examiner considers the selection of such to be mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art.

As to claims 13-15, the above combination teach the seal including a ramp that acts upon the switch. Rand et al. teaches the seal passing above switch 18 including a ramp 16 that act upon the switch means 18 when the canister 2 is moved in the first direction as shown in Figures 8 and 9. In addition, Rand et al. teaches the switch means 44 as being mounted on a circuit board 49 (column 8, lines 17-22) and is acted upon by a ferrule portion 11 of the canister 2, the switch means 44 being isolated from the canister by a second seal 5 (column 4, lines 12-20). Rand et al. also teaches the seal 40 being made of conductive material (sections 47/46). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify O'Connor with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

As to claims 45-48 the above combination discloses a ferrule portion of the canister 11 acting upon a ramp seal 51. The combination continues to teach the counter 40 and ramp seal 51 as being formed in a common component. In addition, the combination discloses a sump for a nozzle of the canister wherein the counter, ramp seal and sump are formed as a common component as shown in Figure 5. The device's common component of the above combination is capable of being injection moldable. In addition, this device's common component is capable of being adaptable to canister holders for a variety of canister shapes and sizes. The common component is adaptable to canister holders for a variety of canister shapes and sizes. In addition, it is considered

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well known in the art that this device is adaptable to canister holders for a variety of canister shapes and sizes for many different users. This device also includes the components including a canister holder, a canister, a mouthpiece, and a counter, wherein the counter is adaptable for use with a canister holder, canister, and a mouthpiece capable of being made of a variety of sizes and shapes. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/4/07